DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 9, 2015

U&U Medical Technology Co., Ltd
Mr. Garfield Wang
General Manager
Dongzhou Village, Hengshanqiao
RM EE1092 1/F Building 1, No 1755
Hongmei Road
Changzhou, Jiangsu
China

Re: K143637
Trade/Device Name: U&U Sterilization Pouch and Roll
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: FRG, JOJ
Dated: August 2, 2015
Received: August 5, 2015

Dear Mr. Wang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See *PRA Statement below.*

510(k) Number *(if known)*
K143637

Device Name
U&U Sterilization Pouch and Roll

Indications for Use *(Describe)*
The U&U sterilization pouch and roll are intended to provide health care workers with an effective method to enclose devices intended for sterilization in steam and Ethylene Oxide (EtO). The recommended gravity steam sterilization cycle parameters are 30 minutes at 121° C . The recommended EtO sterilization cycle is 4 hours at 55° C with a relative humidity between 50%-85% and a sterilant concentration of 600 mg/L. Furthermore, the sterilization pouch and roll maintains the enclosed devices up until 90Days post sterilization. Lastly, the pouch's external chemical ink indicators are designed to indicate to the user that the pouch has undergone either a steam or EtO sterilization process.

STERILIZATION CYCLE:
The recommended gravity steam sterilization cycle parameters
Steam sterilization temperature: 121°C (250 °F)
Steam sterilization time: 30 minutes.

Drying time: 25 minutes
The recommended EtO sterilization cycle parameters
EtO sterilization temperature: 55°C (130 °F)
EtO sterilization time: 4 hour
EtO sterilization humidity: 50% to 85% RH
EtO sterilization concentration: 600mg/L
Aeration time: 8 hours.
Aeration Temperature: 60°C

Sterilization load claim:

Two types of sterilization loads were validated.
Load A: Metal medical instruments and Hand-control pen, the total weight is 24lbs.
Load B: Tubing (Silicone) and Surgical Towels. The total weight is 18lbs.

Type of Use *(Select one or both, as applicable)*

☐Prescription Use (Part 21 CFR 801 Subpart D) [X] Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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PRAStaff@fda. hhs.gov

"An agency may not conduct or sponsor, and a *person is not required to respond to,* a *collection of information unless it displays* a *currently valid OMB number."*

Load Types:

The following matrix is the types of medical instruments used for steam and EtO sterilization：

Medical Device	Steam	EtO Gas
Reusable surgical instruments such as clamps, scissors, retractors, pliers	X	X
Endoscopes (thermostable)	X	X
Endoscopes (thermolabile)	-	X
Reusable containers	X	-
Elastic Products such as Rubber or latex (also combined), siliconelastomer, plastics, closed hollow bodies	X	X
HF-cable and handpieces	X	X
Powertools	X	X
Textile Material such as surgical towels	X	X

Sec 005_510(K) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR §807.92

Date Prepared: **2015-09-09**
Submission Numbers for Pre-Submission: **K143637**

1. Submitter Name and Address:

Name: U&U Medical Technology Co., Ltd
Address: Dongzhou Village,Hengshanqiao,Changzhou,Jiangsu,China
RM EE1092 1/F Building 1, No 1755, HONGMEI Road, Shanghai, China
Contactor Name: Garfield Wang
TEL: +86-13902471751
E-mail: Wangxuebo_11@hotmail.com

US Agent:
Name: CARELIFE (USA) INC.
Address: 1580 Boggs Rd, Suite 500/600 Duluth GA 30096
TEL: 404 6612228
Contact person : Ms. LI QIAN liqian@shanghaicarelife.com

2. Submission Devices Information:

Trade/Proprietary Name: U&U Sterilization Pouch and Roll
Common Name: Sterilization Pouch
Classification name: 1) Sterilization wrap
2) Indicator, Physical/Chemical Sterilization Process
Class: II 21 CFR 880.6850 & 21 CFR 880.2800
FDA review panel code: General Hospital
Product code: 1) FRG 2) JOJ

3. Predicate Devices Information:

Trade Name: SIGMA Sterilization Pouch and Roll
510(K) Number: K102158
Manufacturer: SIGMA Medical Supplies Corp.

4. Devices Description:

The U&U Sterilization Pouch and Roll are manufactured from paper and medical plastic film that are heat sealed on three sides. The fourth side has an adhesive tape that is used to seal the pouch or heat-sealed by the heat-seal machine. The paper conforms to recognized material standards and can be sterilized by steam and Eto. The Sterilization Pouch has the same intended use, Essential Component, Raw material, Sterilization method, manufacturing methods and same technological characteristics as the predicate device. Substantial equivalent to the predicate device was established by physical testing of the sterilized finished devices, as well as, performance of these finished devices (seal strength, package burst, and dye migration).

5. Model numbers of the pouches:

Ref Number	Model Number	Description	Size
UUPP0001	UUPP	STERILIZATION Pouch-Heat-Seal and Self-Seal	3" X 8"
UUPP0002	UUPP	STERILIZATION Pouch-Heat-Seal and Self-Seal	4" X 10.25"
UUPP0003	UUPP	STERILIZATION Pouch-Heat-Seal and Self-Seal	6" X 12.5"
UUPP0004	UUPP	STERILIZATION Pouch-Heat-Seal and Self-Seal	4" X 14"
UUPP0005	UUPP	STERILIZATION Pouch-Heat-Seal and Self-Seal	8" X 16"
UUPP0006	UUPP	STERILIZATION Pouch-Heat-Seal and Self-Seal	6" X 16.5"
UUPP0007	UUPP	STERILIZATION Pouch-Heat-Seal and Self-Seal	10" X 19"
UUPP0008	UUPP	STERILIZATION Pouch-Heat-Seal and Self-Seal	12.5" X 22"
UUPR0001	UUPR	STERILIZATION Roll-Heat-seal	3" X 228'
UUPR0002	UUPR	STERILIZATION Roll-Heat-seal	4" X 228'
UUPR0003	UUPR	STERILIZATION Roll-Heat-seal	6" X 228'
UUPR0004	UUPR	STERILIZATION Roll-Heat-seal	14" X 228'
UUPR0005	UUPR	STERILIZATION Roll-Heat-seal	16.5" X 228'
UUPR0006	UUPR	STERILIZATION Roll-Heat-seal	20" X 228'

5. Intended Use:

The U&U sterilization pouch and roll are intended to provide health care workers with an effective method to enclose devices intended for sterilization in steam and Ethylene Oxide (EtO). The recommended gravity steam sterilization cycle parameters are 30 minutes at 121°C. The recommended EtO sterilization cycle is 4 hours at 55°C with a relative humidity between 50%-85% and a sterilant concentration of 600 mg/L. Furthermore, the sterilization pouch and roll maintains the enclosed devices up until 90 Days post sterilization. Lastly, the pouch's external chemical ink indicators are designed to indicate to the user that the pouch has undergone either a steam or EtO sterilization process.

STERILIZATION CYCLE:

The recommended gravity steam sterilization cycle parameters
Steam sterilization temperature: 121℃ (250 ℉)
Steam sterilization time: 30 minutes.
Drying time: 25 minutes
The recommended EtO sterilization cycle parameters
EtO sterilization temperature: 55℃ (130 ° F)
EtO sterilization time: 4 hour
EtO sterilization humidity: 50% to 85%RH
EtO sterilization concentration: 600mg/L
Aeration time: 8 hours.
Aeration Temperature: 60°C

Sterilization load claim:

Two types of sterilization loads were validated

Load A: Metal medical instruments and Hand-control pen, the total weight are 24lb. The double pouched devices are placed into the baskets.
Load B: Tubing (Silicone) and Surgical Towels. The total weight is 18lbs.

Load Types:
The following matrix is the types of medical instruments used to the sterilization:

Medical Device	Steam	EtO Gas
Reusable surgical instruments such as clamps, scissors, retractors, pliers	X	X
Reusable containers	X	-
Elastic Products such as Rubber or latex (also combined), siliconelastomer, plastics, closed hollow bodies	X	X
HF-cable and handpieces	X	X
Powertools	X	X
Textile Material such as surgical towels	X	X

6. Technological Characteristics:

All testing followed the following standards.
AAMI/ANSI ST77 Containment devices for reusable medical device sterilization
AAMI TIR22 Guidance for ANSI/AAMI/ISO 11607-Packaging for terminally sterilized medical devices-Part 1 and Part 2:2006
AAMI/ANSI/ISO 11140-1 Sterilization of health care products - Chemical indicators - Part 1: General requirements

7. Performance Testing:

Performance testing was conducted to show that the U&U Sterilization Pouch and Roll maintain sterility until the seal of the Pouch/Roll is opened.
Performance Tests

Element	Results
Sterilant Penetration	*PASSED*
Package Integrity	*PASSED*
Maintenance of Package Integrity	*PASSED*
Material Compatibility	*PASSED*
Shelf-Life	*PASSED*
Biocompatibility	*PASSED*
Labeling	*PASSED*
Configurations /Dimensions	*PASSED*
Air permeance	*PASSED*
Maintenance of Sterility	*PASSED*
Endpoint stability of process indicator	*PASSED*
Shelf Life of Process Indicator	*PASSED*
Chemical Indicator Efficacy	*PASSED*
Seal strength	*PASSED*
Peel-open characteristic	*PASSED*
Seal width	*PASSED*
Self seal strength	*PASSED*
Visual inspection	*PASSED*

Ethylene oxide residuals	*PASSED*

8. SUBSTANTIAL EQUIVALENCE DISCUSSION:

Our Sterilization Pouch and the predicate device are same in intended use, components, materials, sterilization, and function.
Side by side testing was conducted on the U&U Sterilization Pouch and Roll and SIGMA Sterilization pouch and roll - K102158 to determine substantial equivalence. Sterilant Penetration, Biocompatibility, Package Integrity, Material Compatibility, Sterility Maintenance were the parameters used to determine substantial equivalence and validate the safety and efficacy of the device.

<table>
<tr><th>Element of Comparison</th><th>Submission Device</th><th>Predicate Device
K102158</th></tr>
<tr><td>Intended Use</td><td>The U&U sterilization pouch and roll are intended to provide health care workers with an effective method to enclose devices intended for sterilization in steam and Ethylene Oxide (EtO). The recommended gravity steam sterilization cycle parameters are 30 minutes at 121 ℃. The recommended EtO sterilization cycle is 4 hours at 55 ℃ with a relative humidity between 50%-85% and a sterilant concentration of 600 mg/L. Furthermore, the sterilization pouch and roll maintains the enclosed devices up until 90Days post sterilization. Lastly, the pouch's external chemical ink indicators are designed to indicate to the user that the pouch has undergone either a steam or EtO sterilization process

STERILIZATION CYCLE:

The recommended gravity steam sterilization cycle parameters
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Sterilization load claim:

Two types of sterilization loads were validated.

Load A: Metal medical instruments and Hand-control pen, the total weight are 24lb. The double pouched devices are placed into the baskets.
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<table><tr><th>Medical Device</th><th>Steam</th><th>EtO Gas</th></tr><tr><td>Reusable surgical instruments such as clamps, scissors, retractors, pliers</td><td>X</td><td>X</td></tr><tr><td>Reusable containers</td><td>X</td><td>-</td></tr></table></td><td>The SIGMA sterilization pouch and roll are intended to provide health care workers with an effective method to enclose devices intended for sterilization in steam and Ethylene Oxide (EtO). The recommended steam sterilization cycle parameters are 30 minutes at 121 ℃. The recommended EtO sterilization cycle is 4 hours at 55 ℃ with a relative humidity between 50%-85% and a sterilant concentration of 600 mg/L. Furthermore, the sterilization pouch and roll maintains the enclosed devices up until 2 years post sterilization. Lastly, the pouch's external chemical ink indicators are designed to indicate to the user that the pouch has undergone either a steam or EtO sterilization process</td></tr>
</table>

	Elastic Products such as Rubber or latex (also combined), siliconelastomer , plastics, closed hollow bodies	X	X		
	HF-cable and handpieces	X	X		
	Powertools	X	X		
	Textile Material such as surgical towels	X	X		
Material Composition	Top Web - Medical Porous Paper Bottom Web - Medical Plastic film(CPP) Bottom Web - Medical two-sided adhesive tape EtO gas indicator ink-Process Indicators class 1 Steam indicator ink-Process Indicators class 1				Top Web - Medical Porous Paper Bottom Web - Medical Plastic film(CPP) Bottom Web -Medical two-sided adhesive tape EtO gas indicator ink-Process Indicators class 1 Steam indicator ink-Process Indicators class 1
Sterilization Cycles	The recommended gravity steam sterilization cycle parameters are 30 minutes at 121 ℃. The recommended EtO sterilization cycle is 4 hours at 55 ℃ with a relative humidity between 50%-85% and a sterilant concentration of 600 mg/L.				The recommended steam sterilization cycle parameters are 30 minutes at 121 ℃. The recommended EtO sterilization cycle is 4 hours at 55 ℃ with a relative humidity between 50%-85% and a sterilant concentration of 600 mg/L.
Configurations /Dimensions	For Pouch: Width: ±0.1″″ Length ± 0.2″″ For Roll: Width: ±0.1″″ Length ± 3%				For Pouch: Width: ±0.1″″ Length ± 0.2″″ For Roll: Width: ±0.1″″ Length ± 3%
Air permeance	The maximum equivalent pore size diameter shall not exceed 50um.				The maximum equivalent pore size diameter shall not exceed 50um.
Sterilant Penetration	Use the EN 868-2:1999 Annex C: Method for the determination of the pore size, the pore size diameter is 40 to 44 um The data is a little higher than the predicated device, The difference can be accepted.				Use the EN 868-2:1999 Annex C: Method for the determination of the pore size, the pore size diameter is 38 to 43 um
Microbial Barrier Properties (Packaging Integrity)	Use ASTM 1608 method, the LRV is more than 3.5 Use ASTM 1929 method, the inspection result is PASS The data is a little higher than the predicated device, The difference can be accepted.				Use ASTM 1608 method, the LRV is 3.3 Use ASTM 1929 method, the inspection result is PASS
Material Compatibility	After sterilization, the materials were not degraded				After sterilization, the materials were not degraded
Toxicological Properties(Biocompatibility, including Sterilant Residue Limits)	Meet ISO10993-4,Haemolysis Test (Direct-contract Method), ISO10993-10, Test for Irritation (Intractaneous Reactivity Test) and ISO10993-10, Test for Skin sensitization (Maximization test)				Meet ISO10993-4,Haemolysis Test (Direct-contract Method), ISO10993-10, Test for Irritation (Intractaneous Reactivity Test) and ISO10993-10, Test for Skin sensitization (Maximization test)
Maintenance of Sterility	90 Days				2 years
Endpoint stability of process indicator	90 Days				2 years
Shelf Life of Process Indicator	18 months				2 years
Drying time	25 minutes				25 minutes
Aeration time	8 hours at 60°C				8 hours at 60°C
Chemical Indicator Efficacy	Changed color EtO- YELLOW to COCOA; Steam- GREEN to PURPLE				Changed color

9. Conclusion:

The performance testing data for the U&U Sterilization Pouch and Roll demonstrates substantial equivalence to the SIGMA Sterilization Pouch and Roll (K102158).

END